visionrt

510(k) Summary

K072171

The following information is provided following the format of 21 CFR §807.92 for the GateCT-RT Respiratory Gating System.

1. Submitter: Vision RT Ltd
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Date summary was prepared: 26th July 2007

OCT 1 ˇ 2007

2. Name of the Device: **GateCT-RT**
Trade/Proprietary Name: GateCT, GateRT
Common or Usual Name: Respiratory Gating System
Classification Name: Medical Charged-particle radiation therapy system accessory.

3. Predicate Devices: Varian RPM Respiratory Gating (K063270); Vision RT's AlignRT (K052682).

4. Description of the Device: The GateCT-RT device is an attachment to radiation therapy treatment systems, simulators and image acquisition devices used for diagnostics and radiation therapy. The GateCT-RT system senses and records the respiratory motion and respiratory state of a patient using real time 3D surface tracking of the patient without the need of any externally positioned markers. Regions to be tracked are selected remotely in a location indicated by the physician on the GateCT-RT workstation. These may be automatically detected during subsequent sessions. GateCT tracks the patient's breathing during CT acquisition in order to facilitate 4DCT reconstruction. GateRT tracks respiratory motion during treatment or imaging and automatically disables the beam when the breathing signal moves outside the user defined gating window. GateCT-RT may also be employed within the monitoring mode of AlignRT to disable the beam automatically if any patient movement is detected which exceeds a user defined tolerance. The Vision RT camera unit is connected to a PC workstation and is used for surface tracking of the patient.

5. Intended Use Statement: The GateCT-RT system is used to obtain tracking of the subject's respiratory pattern for respiratory synchronized image acquisition, and radiation therapy treatment. It can be also used, either independently or in conjunction with Vision RT's AlignRT (K052682), to monitor the patient position during the image acquisition, simulation and treatment and to disable the radiation beam automatically.

6. Summary of the Technological Characteristics: The Substantial Equivalence Comparison Chart provides a comparison of the technological characteristics to those of the predicate devices. The comparison chart demonstrates that the device is substantially equivalent to its predicate devices cited in the table. The chart is located in Tab 8 of the submission.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

Vision RT Ltd.
% Mr. Robert J. Morton, M.S.
Quality and Regulatory Services, Inc.
1244 Fairway Valley Court
LINCOLN CA 95648

OCT 1 ˇ 2007

Re: K072171
Trade/Device Name: GateCT-RT
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: II
Product Code: IYE
Dated: August 1, 2007
Received: August 6, 2007

Dear Mr. Morton:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxx	(Gastroenterology/Renal/Urology	240-276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 894.xxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150
or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K072171

Device Name: GateCT-RT

Indications for Use:

The GateCT-RT system is used to obtain tracking of the subject's respiratory pattern for respiratory synchronized image acquisition, and radiation therapy treatment. It can be also used, either independently or in conjunction with Vision RT's AlignRT (K052682), to monitor the patient position during the image acquisition, simulation and treatment and to disable the radiation beam automatically.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K072171